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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,541	12/17/2001	Zhihong Helena Qi	CER-295	3561

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MUSERLIAN AND LUCAS AND MERCANTI, LLP
600 THIRD AVENUE
NEW YORK, NY 10016

EXAMINER

KHARE, DEVESH

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 07/21/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/024,541

Applicant(s)

QI, ZHIHONG HELENA

Examiner

Devesh Khare

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1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 9-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Applicant's election without traverse of Group 1 (claims 1-8) in Paper No. 5 is acknowledged. Claims 9-12 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. The applicants' substitute specification, received on 06/05/2003, is acknowledged.

Claims 1-8 are currently pending in this application.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 7 are rejected under the second paragraph of 35 U.S.C. 112, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "modified" is a relative term, which renders the claim indefinite. In the absence of the specific modifications to the compound claimed core or distinct language to describe the structural modifications or the chemical names of modified compounds claimed in all occurrences of this invention, the identity of said modified cyclodextrins would be difficult to describe and the metes and bounds of said modified compounds applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

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35 U.S.C. 103(a) rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hedges (Chem. Rev., 1998).

Claims 1-8 are drawn toward a process for forming a cyclodextrin(CD)-guest complex or increasing the amount of guest in cyclodextrin-guest complex, comprising forming a solution of cyclodextrin and a guest molecule in a solvent wherein the cyclodextrin is present at a concentration of 15% (w/w) or above, and the molecular ratio of cyclodextrin to guest is between 1:1 to 10:1, followed by mixing to form CD-guest precipitate and separating the precipitate to recover the complex. Additional claim limitations include a step of drying the precipitate, cyclodextrin is a modified cyclodextrin or an unmodified cyclodextrin, and solvent is water or an organic solvent, or a mixture.

Hedges teaches that the use of a variety of CDs for a very large number of applications is very well known in the art (see Table 1 on page 2038). Hedges discloses that in a complexation of CD-guest, the preferred molecular ratio of cyclodextrin to guest is 1:1 (see page 2035, 1st col. lines 24-27, 3rd para). The reference further teaches that a guest compound can be added into a solution of cyclodextrin in water to form a complex, which can then be collected as a precipitate, the collected precipitate can be dried (see page 2035, col.1 last para – col.2, 2nd para). Hedges discloses that the

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cyclodextrin concentration of 40-50% w/w can be used in a CD-guest complex (see page 2035, col. 2, last para). Hedges discloses that the amount of guest complexed with cyclodextrin can be increase or decrease in terms of its solubility in the complex (see page 2037, col. 2, 2nd para, lines 1-3). Hedges also discloses the modified and unmodified cyclodextrins and their effect in the solubility of the guest compound (see page 2037, 2nd col. 2nd para, mid-end and 3rd para, end part). The use of branched cyclodextrin is disclosed in the CD-guest complex on page 2038, 1st col., 3rd para.). Hedges discloses an example of CD-Pilocarpine complex where cyclodextrin is used at a concentration of 15% (see page 2041, col. 1, last para). Hedges differs from the applicant's invention that Hedges does not teach the full range of cyclodextrin species types recited in claims 3 and 7. Use of a known member of a class of materials in a process is not patentable if other members of the class were known to be useful for that purpose, even though results are better than expected.

It would have been obvious to person having ordinary skill in the art at the time the invention was made, to modify the process of Hedges to increase the yield of a complex of cyclodextrin and guest and to increase the amount of guest complexed of claims 1 and 5 because the art teaches that a guest compound can be added into a solution of cyclodextrin in water to form a complex, which can then be collected as a precipitate. It would be further obvious to increase the yield of CD-guest complex or to increase the amount of guest complexed with cyclodextrin as taught by Hedges. Those skilled in the art would be motivated to obtain the CD-guest complex as the precipitate because this method is used to prove the feasibility of complexation of a particular guest to

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characterize the complex and to scale-up complexation using other methods (see page 2035,col.2, 2nd para, end part).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Devesh Khare whose telephone number is (703)605-

1199. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at 703-308-4624. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D.,JD(3Y).
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July 16,2003


JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600